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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,589	10/31/2003	Jonathan Kagan	VALTX.002A	1885
20995	7590	06/06/2005	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			GHERBI, SUZETTE JAIME J	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/699,589	Applicant(s) KAGAN ET AL.	
	Examiner Suzette J Gherbi	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24-28 is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-23, 29-68 is/are rejected.
- 7) ☒ Claim(s) 5 and 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> . |

DETAILED ACTION

1. Applicant's amendment dated 3/11/05 has been received in application serial number 10/699,589.

Response to Arguments

2. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-4, 6-8, 10-19, 29-35, 37-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Stack et al. 6,675,809. Stack et al. discloses the invention as currently claimed noting figures 17a-19b comprising: An artificial stoma device sized and configured to be installed in an esophagus or stomach: (pouch 302) and a

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gastrointestinal sleeve connected to the artificial stoma device, the gastrointestinal sleeve sized and configured to extend from the stoma device through the stomach and into the intestines of a patient (see col. 9, lines 19-23); wherein the stoma device is adjustable (see self-expanding feature col. 8, lines 15-16, 23-24); wherein the device can be sutureless (via then nitinol expanding and abutting against the tissue); sleeve materials listed are impermeable (inherently impermeable because the invention does not want leakage see col. 3, lines 40-44); with a plurality of points of attachment (figure 18 sutures 310); wherein the device and sleeve are *capable of being* removably connected and collapsed to facilitate passage through the esophagus (see col. 5, lines 22-24).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 9, 20-23, 36, 45-55, 57-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stack et al. in view of Bessler 2004/0039452 and further in view of Frantzen et al. 5,843,164. Stack et al. has been disclosed above and discloses that a bypass tail may extend from the pouch to the pylorus into the small bowel however

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Stack does not disclose a distal anchor that can penetrate surrounding tissue. Bessler teaches gastric bypass sleeve what has a distal end anchor (12 which extends to the duodenum or beyond [0020]. Frantzen teaches a stent for attaching grafts with anchor hooks at the end (20, 34), which are capable of penetrating tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the distal anchor of Bessler and apply it to the distal end of the bypass tail as taught by Stack et al. because the anchor would prevent the sleeve/tail from migrating during peristaltic motion of the stomach. Stack also does not disclose specific widths and/or lengths. As taught by Bessler and is obvious to one having ordinary skill in the art "*the width, length and other parameters of the device will vary, especially according to the patient...*"

Allowable Subject Matter

7. Claim 5 and 56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Claims 24-28 are allowed.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Suzette J-J Gherbi
30 May 2005